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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,242	03/09/2004	Rajesh Pendekanti	16031 (ETH-5022)	1908

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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,242	PENDEKANTI ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/22/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/9/04; 9/22/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to enable one of ordinary skill in the art to make and/or use a device having as its energy source one of microwave, laser, RF or cryoablative energy and having a second jaw for reflecting the ablative energy. It is noted that with respect to reflecting ablative energy, the specification is limited to discussing ultrasonic energy. While the specification mentions that alternative energy sources may be used, it is not disclosed that the alternative energy sources may be used in an embodiment employing a second jaw that reflects that ablative energy. That is, the specification specifically supports a means to reflect ultrasound energy, but fails to provide any mention of the means to reflect any alternative energy means.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 6, 8 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Komiya (4,240,431).

Komiya discloses an apparatus for ablating tissue comprising a first jaw (63 – see Figure 16) having a first ablation surface (66c) for directing ablative energy into tissue, and a second jaw (64) having a second surface (67a). The examiner maintains that the second surface (67a) would inherently reflect a portion of the light energy delivered by the fiber optic. The ablative energy is focused by the optical fiber at the first jaw, and the examiner maintains the shape of the second surface would inherently focus some of the reflected light energy back towards tissue. The ablative energy is laser energy, and the jaws are operative to compress tissue.

Claims 1, 4-8, 11 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al (6,723,092).

Brown et al discloses a forceps device that includes first and second jaws for clamping tissue. Each jaw contains one or more ablative elements for treating tissue, and Brown et al specifically teach that various ablative sources may used. In particular, Brown et al teach the use of RF, ultrasound, microwave, laser or cryosurgical energy to treat tissue (see Abstract). The examiner maintains that certain energy types, in particular microwave, ultrasound and laser, will inherently afford a reflectance off the

second jaw member. It is not clear how RF or cryo-ablative energy may be "reflected". Brown et al also disclose the use of a temperature probe to monitor temperature at the tissue site (col. 6, lines 1-17). As seen in the Figures, the jaws maintain a substantially parallel relationship between open and closed positions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al ('092) in view of the teaching of McClurken et al (6,953,461).

The Brown et al device has been addressed. While Brown et al provides first and second jaw members with ablative energy means, there is no specific teaching of providing a cooling fluid through the jaws.

McClurken et al disclose an analogous forceps device for treating tissue with ablative energy. In particular, McClurken et al teach that it is known to provide a cooling fluid through the jaw members to cool tissue treated with the ablative energy means. The examiner maintains that the fluid passages would inherently operate as a heat exchanger to conduct heat from the jaws away from the apparatus.

To have provided the Brown et al device with a means to provide a cooling fluid to the jaw members to cool tissue as it is being treated with energy would have been an

obvious consideration for one of ordinary skill in the art in view of the teaching of McClurken et al.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al ('092) in view of the teaching of Morrison, Jr (4,074,718).

Brown et al disclose jaw members having ablative surfaces, but fails to disclose a heat sink for conducting heat away from the treatment surfaces as set forth in applicant's claim 3.

Morrison, Jr discloses another forceps device that includes first and second jaws having ablative surfaces thereon. In particular, Morrison, Jr. teaches that it may be advantageous to provide the jaw members with a heat sink (76,78) to conduct heat away from the jaw members.

To have provided the Brown et al forceps device with a heat sink to conduct heat away from the jaw members to protect tissue would have been an obvious modification for one of ordinary skill in the art.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al ('092) in view of the teaching of Bommannan et al (6,775,575).

Brown et al fail to specifically disclose providing the device with a jaw member having a pointed distal tip for piercing tissue.

Bommannan et al disclose an alternative forceps device that delivers ablative energy, and specifically teaches that it is advantageous to provide one of the jaws with a pointed tip (226) to facilitate penetrating tissue.

To have provided the Brown et al forceps with a jaw having a pointed tip to facilitate penetrating tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Bommannan et al.

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al ('092) in view of the teaching of Malecki et al (5,626,607).

Brown et al show a forceps device where the jaws are maintained in a substantially parallel configuration in open and closed positions. However, Brown et al fail to disclose the particular actuation mechanism for performing this function as set forth in applicant's claims.

Malecki et al disclose another forceps device. In particular, Malecki et al disclose the same actuation mechanism for opening and closing the forceps jaws. The examiner maintains that to have provided such an actuation mechanism on any forceps device, including the Brown et al forceps, to afford opening and closing of the jaws while maintaining the jaws in a substantially parallel configuration would have been an obvious consideration for one of ordinary skill in the art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Davison et al (5,322,055) discloses another forceps device that

uses ultrasonic ablative energy, and Mollenauer (6,821,273) discloses another forceps device that includes ablative energy selected from the group of RF, ultrasound and other ablative sources.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Peffley
Primary Examiner
Art Unit 3739

mp
December 13, 2005